

REMARKS

In the Office Action mailed April 8, 2003, the Examiner rejected Claims 1-19 under 35 U.S.C. Section 112 for perceived clarity reasons not relating to patentability. In this regard, Applicant submits that Claim 1 is sufficiently clear since it is directed to an apparatus adapted for automated handling, wherein the apparatus includes a plurality of syringe bodies and a flexible belt fixedly attached to the barrels of the syringe bodies, and wherein the flexible belt attachment facilitates positioning of the syringe bodies in a predetermined orientation (i.e. to facilitate automated handling) with at least one end of each barrel being accessible (e.g. to facilitate automated filling).

With respect to Claim 15, Applicant also believes that the claim language is sufficiently clear. As specified in Claim 15, and as shown in Fig. 2 of the application, a "first portion" of a belt 30 is that which extends between adjacent ones of the syringe bodies S. A "second portion" of the belt 30 is that portion which extends about, or at least partially around, the barrels of the syringe bodies S.

In the Office Action, the Examiner also rejected Claims 1-7 and 9-16 under 35 U.S.C. Section 103(a) as being obvious in view of U.S. Patent No. 3,823,181 to Shaw. Further, the Examiner rejected Claims 17-19 under 35 U.S.C. Section 103(a) as being obvious in view of Shaw in combination with U.S. Patent No. 5,884,457 to Ortiz et al. Applicant submits that all pending claims are allowable over the art.

In particular, and as noted by the Examiner, Shaw fails to disclose an apparatus comprising a plurality of syringe bodies interconnected by a flexible belt that is fixedly attached to the barrels of the syringe bodies. As such, Shaw also fails to disclose an arrangement in which a plurality of syringe bodies are positionable in a predetermined orientation with at least one end of each barrel of the plurality of syringe bodies being accessible.

Rather, Shaw is specifically directed to thermoplastic container blow molding (e.g. bottles) utilizing unfinished pre-forms. In this regard, Shaw provides absolutely no disclosure, suggestion or motivation for utilizing any teachings thereof in a manner that would yield the invention of Claim 1.

Indeed, Shaw fails to disclose or otherwise suggest any medical product applications for its unfinished pre-forms for blow molding. Further, Shaw contemplates that when its unfinished pre-

*As motivation
or suggestion
for combining*

forms are blow-molded into final configurations the blow-molded pre-forms are not even interconnected for further handling (e.g. bottle filling).

In view of the forgoing, Applicant submits that the claimed invention is not obvious in view of Shaw. Further, Applicant is submitting herewith a Declaration under 37 C.F.R. Section 1.132 of Brian E. Baldwin and a Declaration under 37 C.F.R. 1.132 of Randall W. Smith in support of the non-obviousness of Claimed 1 over Shaw. Both of the Declarations are by individuals having at least ordinary skill in the field of medical products for fluid medication administration, and both Declarations state that, as of the time of invention of Claim 1, Shaw does not render the invention of Claim 1 obvious.

In relation to the importance of the claimed invention, Applicant directs the Examiner's attention to Pages 1-6 of the present application which reviews the background problems addressed by and solution provided by the present invention.

Based upon the foregoing Applicant submits that independent Claim 1 should be allowed. Applicant further submits that Claims 2-7 and 9-16 are allowable for the same reasons and additionally since the further combined features thereof are not disclosed or rendered obvious by Shaw. For example, Shaw fails to disclose, suggest or provide any motivation for modifying the teachings thereof in relation to the various syringe body and flexible belt subfeatures stipulated by Claims 2-7 and 9-16.

Ortiz et al. also fails to disclose or suggest the arrangement of Claim 1, much less Claims 17-19. For example, Ortiz et al. fails to disclose an apparatus having a plurality of syringe bodies having barrels interconnected by a flexible belt that is fixedly attached to the barrel of each syringe body. Rather, the only apparatus for handling devices 12 disclosed by Ortiz et al. are feeding magazines 26 within which devices 12 may be supportably and removably positioned. Of note, the feeding magazines 26 are of a rigid, non-flexible construction and are not fixedly attached to the devices 12. Of further note, the feed magazines 26 of Ortiz et al. are utilized to maintain the devices 12 in a desired position relative to a filling machine 10.

In addition to the respective shortcomings of Shaw and Ortiz et al., Applicant submits that such references provide absolutely no suggestion or motivation to combine the teachings thereof, much less in a manner that would yield the invention of Claim 1. In this regard, and as noted above, Shaw fails to disclose or suggest that the unfinished performs thereof could be used or otherwise modified for medical product applications. Further, Ortiz et al. actually teaches away the apparatus from Claim 1 since it relies on the use of rigid feeding magazines 26 to position devices 12 relative to a filling station 10. Applicant submits that, upon consideration of Ortiz et al., one skilled in the art would in no way be motivated to replace the rigid feeding magazines 26 of Ortiz et al. with a flexible belt fixedly interconnected to the barrels of a plurality of syringe bodies as taught by Claim 1 since such an arrangement simply would not be workable in conjunction with the filling station 10 taught by Ortiz et al. For example, a flexible belt could not supportably position the devices 12 relative to filling station 10. *

For the record, Applicant notes that it is clear that the prior art must teach or otherwise motivate a combination of prior art references. For example, in the CAFC decision of *In re Anita Dembiczak and Vincent Zinbarg*, 175 F.3d 994, U.S.P.Q.2D (BNA) 1614 (Fed. Cir. 1999) the Court stated:

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir. 1985) (district court’s conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 (“strict observance” of factual predicates to

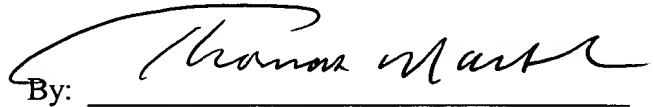
obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case the Board fell into the hindsight trap.

Applicant submits that in the present case the Examiner's combination of Shaw and Ortiz et al. is the result of inappropriate hindsight analysis and, for the various reasons noted above, Applicant respectfully requests withdrawal of the rejection of Claims 17-19.

Based upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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